# IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA Bluefield Division

STATE OF WEST VIRGINIA ex rel. DARRELL V. MCGRAW, JR., ATTORNEY GENERAL,

Plaintiff,

Civil Action No. 101-0557

v.
PURDUE PHARMA L.P.;
PURDUE PHARMA INC.;
PURDUE FREDERICK COMPANY;
ABBOTT LABORATORIES;
ABBOTT LABORATORIES, INC.,

Defendants.

# **NOTICE OF REMOVAL**

PLEASE TAKE NOTICE that pursuant to 28 U.S.C. §§ 1441 and 1446, defendants,

Purdue Pharma L.P.; Purdue Pharma Inc; and The Purdue Frederick Company (which defendants are collectively referred to as "Purdue"); and Abbott Laboratories and Abbott Laboratories Inc.

(collectively "Abbott") hereby give notice of removal of the above-captioned action, Civil Action No. 01-C-137-S, pending in the Circuit Court of McDowell County, West Virginia, to this Court. In support of removal, defendants state as follows:

1. This Notice of Removal is timely pursuant to 28 U.S.C. § 1446(b), in that the complaint in this action was filed on June 11, 2001. Upon information and belief, no service has yet been effectuated. This Notice of Removal is being filed within thirty (30) days of the first

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date on which any of the defendants received a copy of the complaint ("Compl.") through service or otherwise.

- 2. The Circuit Court of McDowell County is located within the Southern District of West Virginia, Bluefield Division.
- 3. Pursuant to 28 U.S.C. § 1446(a), a copy of all process, pleadings, and orders served upon defendants, which papers include the summonses and complaint, is attached hereto as *Exhibit A*.
- 4. This court has original federal-question jurisdiction of this action under 28 U.S.C. § 1331, and this action is therefore removable to this Court on that basis pursuant to 28 U.S.C. § 1441(a). This lawsuit involves claims regarding OxyContin® Tablets, a highly-regulated Schedule II controlled narcotic substance federally approved for use in treating pain. *See* 21 U.S.C. § 812(c); 21 C.F.R. § 1308.12(b)(1), (2); *see also* 55<sup>th</sup> Physician's Desk Reference, "OxyContin®", 2697–2701 (2001). The sole active ingredient in OxyContin® is oxycodone. Every aspect of the manufacture, promotion, and distribution of OxyContin® is subject to comprehensive federal regulation.
- 5. Plaintiff in its complaint asserts claims effectively seeking to challenge the decision by federal regulatory authorities to authorize the manufacture and distribution of OxyContin®. The Controlled Substances Act squarely controls the prescription of OxyContin® by physicians. 21 U.S.C. § 829(a). The DEA's regulations under the Act limit prescriptions for OxyContin® to a "legitimate medical purpose" by a physician who is "acting in the usual course of [his or her] professional practice." 21 C.F.R. § 1306.04(a). Physicians are prohibited by federal law from writing prescriptions for OxyContin® to obtain general supplies for dispensing

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directly to patients, <u>Id.</u> at § 1306.04(b). Under federal law, prescriptions for OxyContin® may not be refilled. 21 U.S.C. § 829(a); 21 C.F.R. § 1306.12.

- 6. In addition, the federal government controls the amount of oxycodone that Purdue is permitted to purchase each year. The DEA exercises this federal control by fixing procurement quotas that limit the amount of oxycodone Purdue can acquire, which in turn limits the amount of OxyContin® Purdue can manufacture. The fixed quota for oxycodone is established by the DEA based on its determination of the amount of oxycodone needed to provide for the estimated medical needs . . . of the United States. 21 U.S.C. § 826. Thus, Purdue manufactures the precise amount of OxyContin® permitted by the DEA. Purdue is prohibited by federal law from manufacturing any greater quantity of OxyContin®.
- 7. Among the allegations in the complaint are charges that defendants wrongfully induced physicians to prescribe OxyContin® (e.g., Compl. at ¶ 25), and that "patients have been and are being exposed to, unnecessarily, the risk of severe and disabling addiction, actual addiction, the consequences of addiction, and other adverse medical conditions." (Id. at ¶ 2.) Plaintiff's claim that defendants improperly encouraged the prescription of OxyContin® necessarily involves the substantial federal issue of the interpretation of what constitutes a "legitimate medical purpose" under 21 C.F.R. § 1306.04(a) and other DEA regulations. Similarly, the question of whether the quantity of OxyContin® manufactured and distributed was appropriate for legitimate medical needs or not (as plaintiff must contend) is both substantial and central to plaintiff's complaint.

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The DEA procurement quota permitting Purdue to acquire oxycodone includes quantities intended for use in both controlled-release and immediate-release formulations, as well as for products exported from the United States.

- 8. The manufacture and distribution of OxyContin® is governed by additional federal regulatory control pursuant to the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 321 *et seq.*. (*See, e.g.*, Compl. at ¶ 56 (challenging the "production, promotion and marketing" of OxyContin®)). Yet the FDA, by approving the New Drug Application for OxyContin®, has specifically found OxyContin® to be safe and effective for its approved indications when prescribed by a licensed physician holding a valid Drug Enforcement Administration ("DEA") registration number, and when used as directed pursuant to the FDA-approved prescription information.
- 9. Similarly, the relief sought by plaintiff, in the form of additional warnings to the public regarding OxyContin® (see, e.g., Compl. at ¶ 54 (H) (1)), raises a substantial question of federal law. The specific language appearing on the warnings accompanying OxyContin® is carefully prescribed by the FDA. Any change in that warning language would require advance evaluation and approval by the FDA under the FDCA. Furthermore, the FDA has an effective administrative system (i.e., a citizen petition), see 21 C.F.R. § 10.30, for considering whether the prescribing information for approved new drugs should be changed. That administrative system is the only permissible vehicle for the changes plaintiff is seeking in its complaint.
- 10. Under 28 U.S. C. § 1441 and principles of supplemental jurisdiction under 28 U.S.C. § 1367, where, as here, any portion of the action arises under federal law, the defendants have the right to remove the entire action to this Court.
- 11. Pursuant to 28 U.S.C. § 1446(d), a copy of this Notice of Removal is being filed with the Circuit Court of McDowell County.

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12. All defendants join in this removal.

Dated: June \_\_\_\_\_, 2001

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Counsel for PURDUE PHARMA L.P.; PURDUE PHARMA INC.; PURDUE FREDERICK COMPANY; ABBOTT LABORATORIES; and ABBOTT LABORATORIES, INC.

#### **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of the foregoing Notice of Removal was mailed by ordinary U.S. mail, postage prepaid, this 21 day of June, 2001 to:

Frances Hughes
Managing Deputy Attorney General
Office of the Attorney General
Building 1, Room 26-E
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Charleston, WV 25305

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Sally W. Childers, Clerk Circuit Court of McDowell County P.O. Box 400 Welch, WV 24801-0400

W. Henry Jernigan, Jr. (WV State Bar #1884)

EXHIBIT A

CASE 01-C-137

MCDOWELL

STATE OF WV.

vs. PURDUE PHARMA L.P.

LINE DATE ACTION

1 06/11/01 COMPLAINT FILED.

STATE OF WEST VIRGINIA COUNTY OF McDOWELL, TO WIT:

I, Sally W. Childers, Clerk of the Circuit Court of McDowell County, West

Virginia, do hereby certify that the foregoing is a true and correct copy from the records
in my office as the same exists therein.

IN TESTIMONY WHEREOF, I hereunto place my hand and affix the official seal of this Court, at Welch this the <u>21st</u> day of <u>June</u> 20 01.

CLERK

DEPUTY CLERK

# IN THE CIRCUIT COURT OF MCDOWELL COUNTY, WEST VIRGINIA

STATE OF WEST VIRGINIA ex rel. DARRELL V. MCGRAW, JR., ATTORNEY GENERAL,

Plaintiff,

Civil Action No. <u>01-C-137-5</u>

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; PURDUE FREDERICK COMPANY; ABBOTT LABORATORIES; ABBOTT LABORATORIES, INC.,

v.

Defendants.

#### COMPLAINT

The State of West Virginia ("the State"), by and through Darrell V. McGraw, Jr., the duly elected and current Attorney General, brings this action upon information and belief, and states for its Complaint as follows:

#### I. INTRODUCTION

- 1. The State of West Virginia spends hundreds of millions of dollars each year to provide or pay for health care and other necessary services and programs on behalf of indigents and other eligible citizens, including payments for the prescription drug OxyContin, which is manufactured, marketed, promoted, sold and/or distributed by the Defendants.
- 2. OxyContin is approved for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Defendants have

manufactured, promoted and marketed OxyContin for the management of pain by making misrepresentations or omissions regarding the appropriate uses, risks, and safety of OxyContin. Accordingly, physicians, pharmacists, and patients have not been provided with accurate information about the appropriate uses and risks of the drug. As a result, physicians, pharmacists, and patients have been unable to appropriately evaluate the relevant risks and benefits of OxyContin and patients have been and are being exposed to, unnecessarily, the risk of severe and disabling addiction, actual addiction, the consequences of addiction, and other adverse medical conditions. Moreover, the rising numbers of persons addicted to OxyContin have led to a dramatic increase of social problems, including drug abuse and criminal acts to obtain OxyContin. Consequently, public health has been significantly and negatively impacted due to the inappropriate use of OxyContin.

- 3. As a further consequence of Defendants' conduct, the State spends millions of dollars each year to pay for excessive prescription costs and to pay health care and medical costs and provide necessary services and programs on behalf of indigents and other eligible citizens who have used or will use OxyContin and have suffered or will suffer deleterious health effects therefrom.
- 4. This action is thus brought pursuant to constitutional, statutory, common law and/or equitable authority for the purposes of, inter alia, (i) recovering restitution and reimbursement for all the costs the State has incurred in paying excessive and unnecessary prescription costs related to OxyContin; (ii) recovering restitution and reimbursement for all the costs expended for health care services and programs associated with the diagnosis and treatment of adverse health consequences of OxyContin use, including, but not limited to, addiction; (iii)

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and unnecessary prescription costs related to OxyContin; (iv) obtaining injunctive relief and damages arising from defendants' violations of the West Virginia Consumer Credit and Protection Act, and other applicable law, including, but not limited to, injunctive relief to stop defendants' promotion and marketing of OxyContin for inappropriate uses: (v) disgorgement: (vi) obtaining civil penalties for each violation under the West Virginia Consumer Credit and Protection Act; (vii) recovering damages as statutorily permitted by law under the West Virginia Antitrust Act; (viii) creation of a court-supervised fund to finance a comprehensive medical monitoring program; and (ix) obtaining such other relief as will provide the State a full and complete remedy.

#### II. PARTIES

- 5. The State is governed by the Constitution and laws of the State of West Virginia. and the State is entitled to bring this action pursuant to law. This suit concerns matters of statewide interest. Darrell V. McGraw, Jr. is the Attorney General of the State of West Virginia ("Attorney General") and is duly authorized by the Constitution and the statutes of the State of West Virginia to pursue this action.
- 6. The State, as an employer that makes available health coverage for its employees pursuant to statutory and contractual obligations, is mandated by law to establish a group hospital and surgical insurance plan or plans, and a group prescription drug plan. The State has paid and continues to pay substantial sums of money for excessive prescription costs and health care costs related to OxyContin. These increased expenditures have been caused by the Defendants.

- 7. The State has expended and will expend substantial sums of money to fund and promote wellness and healthy lifestyle programs in order to reduce health care costs including, but not limited to, programs and activities to address drug addiction. These programs and activities are statutorily mandated as part of the public employees medical insurance programs. These expenditures have been and will be increased by the unlawful actions of the Defendants.
- 8. Defendant Purdue Pharma L.P. is a limited partnership with its principal place of business located at One Stamford Forum. Stamford. Connecticut. At all times relevant hereto. Purdue Pharma L.P. was in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing OxyContin throughout the State of West Virginia, and its actions have affected commerce within this county and the State of West Virginia.
- 9. Defendant Purdue Pharma Inc. is a Delaware corporation with its principal place of business located at One Stamford Forum, Stamford. Connecticut. At all times relevant hereto, Purdue Pharma Inc. was in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing OxyContin throughout the State of West Virginia. and its actions have affected commerce within this county and the State of West Virginia. Purdue Pharma Inc. is the general partner of Purdue Pharma, L.P., and at all relevant times supervised and managed the operations and affairs of its subsidiary and affiliate, Purdue Pharma, L.P.
- 10. Defendant Purdue Frederick Company is a Delaware corporation with its principal place of business located at One Stamford Forum, Stamford, Connecticut. At all times relevant hereto, Purdue Frederick was in the business of designing, testing, manufacturing, labeling,

advertising, promoting, marketing, selling and/or distributing OxyContin throughout the State of West Virginia, and its actions have affected commerce within this county and the State of West Virginia

- Defendant Abbott Laboratories is an Illinois corporation with its principal place of business located at Abbott Park. North Chicago. Illinois. At all times relevant hereto. Abbott was in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing OxyContin throughout the State of West Virginia, and its actions have affected commerce within this county and the State of West Virginia. At all times relevant hereto Abbott Laboratories supervised and managed the operations and affairs of its affiliate and subsidiary, Abbott Laboratories, Inc.
- place of business located at Abbott Park, North Chicago, Illinois. At all times relevant hereto, Abbott was in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing OxyContin throughout the State of West Virginia, and its actions have affected commerce within this county and the State of West Virginia.

# III. JURISDICTION AND VENUE

- 13. Jurisdiction is proper in this Court pursuant to W. Va. Code § 56-3-33a.
- 14. The Defendants (directly or through agents who were at the time acting with actual and/or apparent authority and within the scope of such authority) transacted business in McDowell County and throughout the State of West Virginia.
- 15. Venue is proper pursuant to W. Va. Code § 46A-7-114 and W. Va. Code § 47-18-15 and other state law, because all or part of the Defendants' acts and conduct alleged herein

occurred within and predominantly affected McDowell County and the State of West Virginia.

and because the Defendants do business in McDowell County and throughout the State of West Virginia.

As a result of the manufacture, distribution, marketing, promotion, delivery and sale of OxyContin to consumers within McDowell County and throughout the State of West Virginia, Defendants, directly or through their subsidiaries, affiliates or agents, obtained the benefits of the laws of the State of West Virginia and the West Virginia market for painkillers.

#### IV. FACTS

- OxyContin is an opioid analgesic drug, sold in tablet form, which is a controlled-release oral form of oxycodone hydrochloride. Oxycodone is a morphine-like drug.
- 18. OxyContin is approved for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days.
- 19. Defendant Purdue Pharma L.P. developed and patented OxyContin, which was launched in December 1995. OxyContin initially was available in 10 mg., 20 mg., and 40 mg. tablet strengths. In 1997, OxyContin 80 mg. tablets became available, and in July 2000, 160 mg. tablets became available. In May 2001, the 160 mg. tablets of OxyContin was discontinued. Defendants Abbott Laboratories and Abbott Laboratories, Inc. co-promote OxyContin.
- 20. Because of its controlled-release or time-release formulation. OxyContin tablets are taken every twelve (12) hours, as opposed to short-acting pain medications which must be taken every three to six hours. However, because of its controlled-release or time-release formulation, OxyContin contains far more milligrams of OxyCodone than other drugs containing

OxyCodone on the market. For example, the 160 mg. form of OxyContin contains as much of the active ingredient Oxycodone as 32 Percocet pills.

- 21. OxyContin is a federally controlled. Schedule II drug, meaning that: (1) it has a high potential for abuse; (2) it has currently been accepted for medical use in the United States with severe restrictions: and (3) the abuse of the drug may lead to severe psychological or physical dependence. Because OxyContin is a Schedule II drug, if a patient receives a prescription for OxyContin, that person must bring the written prescription to a pharmacy. The prescription cannot be called in to the pharmacy by the patient's doctor.
- 22. Following the launch of the drug in December 1995, sales quickly skyrocketed. and during the year 2000, just four (4) years from the time of its launch, OxyContin ranked 36th in sales in the United States of all prescription medications with total sales of \$601.128.000 resulting from 3.505,000 prescriptions that year. Total sales of OxyContin have surpassed \$1 billion in the United States.
- 23. The enormous sales volume of OxyContin was due primarily to Defendants' aggressive marketing strategy to physicians, pharmacists and patients. That strategy, however, which relied heavily on highly coercive tactics, misrepresented the appropriate uses of OxyContin and failed to adequately disclose and discuss the safety issues and possible adverse effects of OxyContin use.
- 24. For example, on May 11, 2000, the United States Food and Drug Administration issued an official warning letter to Purdue Phama ordering it to cease use of a Purdue Pharma advertisement for OxyContin, which stated and/or implied that OxyContin could be used to treat arthritis patients without first using milder drugs: "You present the headline, 'Proven Effective

in Arthritis Pain' on the first page of the journal ad. followed by the results of a study conducted in 133 patients with moderate to severe osteoarthritis on the second page. This presentation suggests that OxyContin had been studied in all types of arthritis and can be used as first-line therapy for the treatment of osteoarthritis. . . You should immediately discontinue the use of this journal advertisement and all other promotional materials for OxyContin that contain the same or similar claims or presentations." Purdue later withdrew the advertisement in question.

- 25. Similarly, Defendants' sales representatives (also known as detail persons) used highly coercive and inappropriate tactics to attempt to get physicians and pharmacists to prescribe OxyContin and to fill prescriptions for OxyContin, often when it was not called for. According to press reports, Defendants and their employees or agents have represented to physicians and pharmacists that OxyContin "was safe enough to treat short-term pain", that it should be prescribed to elderly women with osteoarthritis, and that it should be prescribed "for everything". In addition, Defendants and their employees or agents have suggested to pharmacists that they can get in trouble if they do not fill prescriptions, even if they believe someone may be an abuser of the drug.
- 26. Indeed, a Purdue spokesperson acknowledged that many of the thousands of sales representatives hired since the 1990's were unaware of the constraints imposed by the American Medical Association's ethics guidelines, which were created to deter coercive and inappropriate tactics of sales representatives.
- 27. In addition, Defendants courted physicians and their allegiance to the drug, by paying doctors' transportation and hotel costs to attend weekend meetings to discuss pain management, where Defendants would recruit doctors and pay them fees to speak to other

doctors at the more than 7,000 "pain management" seminars that they sponsored around the United States. At those seminars, Defendants marketed OxyContin as a safe and effective way in which to treat all manner of pain, including minor pain, yet failed to provide adequate information or any mention of the fact that OxyContin was intended to treat only moderate to severe pain and failed to warn of OxyContin's potential for abuse.

- 28. Moreover, despite claiming that they did not market OxyContin directly to consumers. Defendants did, in fact, market the drug in that manner. In particular, Defendants financed an Internet site called "Partners Against Pain," which promoted OxyContin to the public.
- 29. As a result of these aggressive marketing tactics, Defendants achieved their purpose. OxyContin rapidly became one of the most widely used painkillers in the State and throughout the country.
- 30. As a result of Defendants' inappropriate marketing of OxyContin, the drug has been inappropriately prescribed and used, unnecessarily putting people at risk of addiction of OxyContin, causing many users of the drug to become addicted to OxyContin and suffering the consequences of addiction.
- 31. Moreover, Defendants were and are facilitating the inappropriate use of OxyContin by supplying pharmacies in Mexico with OxyContin, because they are aware that members of the public can obtain OxyContin from these pharmacies without a prescription.
- 32. Upon information and belief, Defendants failed to incorporate into the product formulation any features that would have reduced the risk of bypass, diversion and abuse, all leading to the risk of addiction. Accordingly, as the use of OxyContin mushroomed (particularly

because of prescription for inappropriate uses), so too did the numbers of people who were being put at risk of addiction to the drug and/or who were becoming addicted to the drug. OxyContin can be and is abused by crushing and/or dissolving the product, which creates a feeling of euphoria similar to that experienced when taking heroin. Despite their awareness of the abuse of OxyContin by crushing and/or dissolving of the product. Defendants failed to take steps to reformulate OxyContin to prevent the abuse of the drug in this manner.

- 33. Despite their awareness of the rising tide of abuse of OxyContin in the above-mentioned ways. Defendants continued to aggressively market OxyContin and failed to take appropriate measures to ensure that OxyContin was prescribed only in appropriate circumstances.
- 34. Ultimately, the inappropriate use and abuse of OxyContin engendered by Defendants' marketing practices grew to such a level that Federal drug enforcement officials asked Purdue to limit distribution of OxyContin to doctors who manage pain. This was the first time that the DEA has targeted a specific prescription drug to curb its misuse.
- 35. As a result of the excessive and unnecessary prescriptions of OxyContin. employees of the State of West Virginia and other eligible participants in the Public Employees Insurance Agency (P.E.I.A.) programs have been inappropriately prescribed OxyContin. and the State and P.E.I.A. have incurred excessive and unnecessary expenses as a result thereof. For example, OxyContin in the 40mg, and the 20mg, tablets ranked within the top 100 drugs paid for by P.E.I.A. between July 1, 2000 and March 31, 2001, ranking 53<sup>rd</sup> and 58<sup>th</sup>, respectively. During that same period, P.E.I.A. paid approximately \$440,000 for those two forms of OxyContin.
- 36. As a result of the excessive and unnecessary prescriptions of OxyContin,

  Medicaid recipients in the State of West Virginia have been inappropriately and unnecessarily

prescribed OxyContin, and the State and the Department of Health and Human Resources (D.H.H.R.) have incurred excessive and unnecessary expenses as a result thereof.

- 37. D.H.H.R. spends 2% of its total pharmaceutical expenditures on OxyContin. For the calender year 2000, D.H.H.R. spent \$4.617.114.15 for 27,771 prescriptions of OxyContin in its various forms (i.e., 160 mg., 80 mg., 40 mg., 20 mg. And 10 mg.).
- 38. OxyContin (40mg.) ranked 9 out of the top 10 highest paid drugs paid for by D.H.H.R. in the quarter ending December 31, 2000.
- Many of the southern counties of West Virginia have suffered from exposure to the dangers of OxyContin in greater proportion than the rest of the State. For example, in the year 2000, ten of the 55 counties in West Virginia, all in the southern part of the State, accounted for approximately 48% of the total prescriptions paid for by D.H.H.R. These counties include Kanawha (7.56%), Mercer (6.71%), McDowell (5.7%), Cabell (5.47%), Logan (4.46%), Wyoming (4.37%), Raleigh (4.33%), Greenbrier (4.12%), Wayne (3.8%), Mingo (1.8%).
- 40. For example, for McDowell County, during the year 2000, D.H.H.R. paid approximately \$263,321.49 for 1785 prescriptions and the payments totaled 5.7% of the total amount spent on OxyContin. McDowell County had 6.01% of the total number of recipients and 6.43% of the prescriptions written in this State and paid for by D.H.H.R.
- 41. By way of further example, for Wyoming County, during the year 2000, D.H.H.R. paid approximately \$201,830.39 for 1332 prescriptions and the payments totaled 4.37% of the total amount spent on OxyContin by D.H.H.R.
- 42. During the period between April, 2000 and April, 2001, the West Virginia Workers Compensation Division spent approximately \$2,234,648.00 for OxyContin

prescriptions in its various forms (*i.e.*, 160 mg., 80 mg., 40 mg., 20 mg. And 10 mg.). As a result of the excessive and unnecessary prescriptions of OxyContin, workers in the State of West Virginia have been exposed to the risks of addiction, actual addition and the consequences of addiction, and have faced barriers to work rehabilitation and to returning to their employment. Consequently, the State and the Workers' Compensation Division have incurred excessive and unnecessary expenses, as well as other payments made by the Division as a result of the lost time from work suffered by users of OxyContin.

As a result of the excessive, inapprorpriate and unnecessary prescriptions of OxyContin, citizens and consumers of West Virginia, who have legitimately and legally paid for OxyContin, have incurred actual damages and excessive costs as a result thereof.

#### V. CAUSES OF ACTION

#### COUNT I

# (VIOLATION OF THE CONSUMER CREDIT PROTECTION ACT)

- 44. The State realleges and incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows:
- The State has, through its legislature, enacted Title 6 of the West Virginia

  Consumer Credit Protection Act, entitled "General Consumer Protection", which is designed to protect consumers from fraudulent and deceptive practices. W. Va. Code §§ 46A-6-101 to -110, 46A-7-102 and 46A-7-108.
- 46. The Attorney General of the State of West Virginia is specifically charged with the administration of W. Va. Code §§ 46A-6-101, et seq., and may act on his own motion as the

agent and legal representative of the State in civil proceedings to enforce said statute. W. Va. Code §§ 46A-6-103, W. Va. Code §§ 46A-7-102, 108, 110, 111.

- 47. In violation of W. Va. Code. §46A-6-101, et seq., Defendants made untrue, deceptive or misleading representations of material facts to, and omitted and/or concealed material facts from, the State and citizens of West Virginia in marketing and promotional campaigns and materials, among other ways, regarding the appropriate use and safety of OxyContin.
- 48. The misrepresentations and omissions described herein were likely to deceive and/or confuse citizens into requesting OxyContin from their physicians and into purchasing OxyContin.
- 49. Defendants knew or should have known that the use of OxyContin could cause serious and potentially life threatening addiction and consequences of addiction and other adverse effects.
- Defendants knew of the growing public acceptance of the misinformation and misrepresentations regarding the uses, safety and efficacy of OxyContin, but remained silent because their appetite for significant future profits far outweighed their concern for the health and safety of the citizens of West Virginia.
- As a proximate result of the acts of unfair and deceptive business practices set forth above, the defendants have exposed the citizens of West Virginia to the dangers of OxyContin and the State has paid excessive prescription costs and health care costs related to OxyContin and its use.

- 52. The illegal conduct alleged in this Complaint is continuing, with no indication that Defendants will cease.
- 53. The actions of Defendants in manufacturing, marketing, promoting, distributing and selling OxyContin in West Virginia constitute violations of the West Virginia Consumer Protection Act in that they are unfair methods of competition and/or unfair deceptive acts or practices pursuant to W. Va. Code § 46.A-6-102(f). These unfair methods of competition and/or deceptive acts are as follows:
  - A. Causing likelihood of confusion or misunderstanding as to the sources, sponsorship, approval or certification of goods or services. W. Va Code §46A-6-102(f)(2).
  - B. Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or qualities that they do not have. W. Va. Code §46A-6-102(f)(5).
  - C. Engaging in any other conduct which similarly creates a likelihood of confusion or of misunderstanding. W. Va. Code  $\S$  46A-6-102(f)(12).
  - D. The act, use or employment by any person of any deception, fraud, false pretense, false promise or misrepresentation, or the concealment, suppression or omission, of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any goods or services, whether or not any person has in fact been misled, deceived or damaged thereby. W. Va. Code §46A-6-102(f)(13).
- 54. Wherefore the State prays for relief and judgment against the defendants, jointly and severally, as follows:
- A. For restitution and reimbursement sufficient to cover all prescription costs the State has incurred related to OxyContin due to defendants' wrongful conduct, with said amount to be determined at trial;

- B. For restitution and reimbursement sufficient to cover all costs expended for health care services and programs associated with the diagnosis and treatment of adverse health consequences of OxyContin use, including, but not limited to, addiction due to defendants wrongful conduct, with said amount to be determined at trial:
- C. For restitution and reimbursement for all the prescription costs consumers have incurred related to OxyContin:
- D. For equitable and/or injunctive relief and damages arising from defendants' violations of the West Virginia Consumer Credit and Protection Act, including but not limited to injunctive relief to stop defendants' promotion and marketing OxyContin for inappropriate uses in West Virginia, currently and in the future:
  - E. For disgorgement;
- F. For civil penalties for each violation under the West Virginia Consumer Credit and Protection Act:
- G. For pre-judgment interest, as well as the State's reasonable attorneys' fees, expert witness fees and other costs of this action;
- H. For a fund establishing a medical monitoring program due to the increased susceptibility to injuries and irreparable threat to the health of OxyContin users resulting from their exposure to OxyContin which can only be mitigated or addressed by the creation of a Court-supervised fund, financed by Defendants and which will:
  - (1) Notify individuals who use or used OxyContin of the potential harm from OxyContin;

- (2) Aid in the early diagnosis and treatment of resulting injuries through ongoing testing and monitoring of OxyContin use;
- (3) Fund studies and research of the short and long term effects of OxyContin and the possible cures and treatments for the detrimental effects of using OxyContin:
- (4) Accumulate and analyze relevant medical and demographic information from OxyContin users including, but not limited to the results of testing performed on them;
- (5) Create, maintain and operate a "registry" in which relevant demographic and medical information concerning all OxyContin users is gathered, maintained and analyzed; and
- (6) Gather and forward to treating physicians information related to the diagnosis and treatment of injuries which may result from using OxvContin.
- I. For such other and further relief, as the Court deems just and proper, to which the State may be entitled.

#### COUNT II

#### (CONTINUING PUBLIC NUISANCE)

- 55. The State realleges and incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows:
- 56. Defendants hereto, individually acting through their employees and agents, and in concert with each other, have created and continue to perpetuate and maintain a public nuisance

by their massive production, promotion and marketing of OxyContin for use by citizens of West Virginia. Defendants knew or should have known that their conduct would cause hurt or inconvenience to the countless numbers of OxyContin users in the State of West Virginia by subjecting those persons to the risks of addiction, actual addiction and other adverse consequences of OxyContin use.

- Defendants have negligently, intentionally and/or unreasonably interfered with the right of the countless number of OxyContin users to be free from unwarranted injury, disease and sickness and have caused ongoing damage, hurt or inconvenience to the countless number of citizens of West Virginia who use, have used or will use OxyContin in that such people have been exposed to the risk of addiction of OxyContin, have become addicted to OxyContin, and/or have suffered other adverse consequences from the use of the drug and countless others will suffer the same fate in the future as Defendants' conduct is continuing.
- As a direct result of the conduct of each of the Defendants as set forth above,

  Defendants have negligently, intentionally and/or unreasonably interfered with the public's right
  to be free from unwarranted injury, disease and sickness, and have caused ongoing damage, hurt
  or inconvenience to the public health, the public safety and the general welfare of the citizens of
  West Virginia.
- 59. The health and safety of the citizens of West Virginia, including those who use, have used or will use OxyContin, is a matter of great public interest and of legitimate concern to the State and its citizens.

- 60. The public nuisance created, perpetuated and maintained by Defendants can be abated and further occurrence of such harm and inconvenience can be prevented.
- As a direct result of the acts of the Defendants in creating, perpetuating and maintaining the public nuisance hereinabove described, the State has suffered economic harm in the expenditure of massive sums of monies and will continue to suffer said harm unless and until the public nuisance hereinabove described is abated.
- 62. Wherefore the State prays for relief and judgment against the defendants, jointly and severally, as follows:
- A. For restitution and reimbursement sufficient to cover all prescription costs the State has incurred related to OxyContin due to defendants' wrongful conduct, with said amount to be determined at trial:
- B. For restitution and reimbursement sufficient to cover all costs expended for health care services and programs associated with the diagnosis and treatment of adverse health consequences of OxyContin use, including but not limited to addiction due to defendants wrongful conduct, with said amount to be determined at trial;
- C. For restitution and reimbursement for all the prescription costs consumers have incurred related to OxyContin;
- D. For such other and further extraordinary equitable, declaratory and/or injunctive relief as permitted by law as necessary to assure that the State has an effective remedy and to stop defendants' promotion and marketing of OxyContin for inappropriate uses in West Virginia currently and in the future;

- E. For pre-judgment interest, as well as the State's reasonable attorneys' fees. expert witness fees and other costs of this action;
- F. For such other and further relief, as the Court deems just and proper, to which the State may be entitled.

# COUNT III

#### (UNJUST ENRICHMENT/RESTITUTION)

- 63. The State realleges and incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows:
- 64. Many of West Virginia's citizens who use or have used OxyContin are or were poor, undereducated and unable to provide for their own medical care. These citizens rely or relied upon the State to provide their medical care, facilities and services, which reliance results in an extreme burden on the taxpayers and the financial resources of the State. Taxpayers of the State have thus indirectly expended millions of dollars for their fellow citizens for the unnecessary and excessive prescription costs and health care costs and other related programs and services associated with OxyContin.
- 65. The State is responsible for the costs of prescription, health care and medical costs for Medicaid recipients pursuant to the State Medicaid Plan and statute administered by the Department of Health and Human Resources. The State is also responsible for prescription, health care, medical costs, rehabilitation and work-related programs and services of certain of its citizens in connection with programs administered by the Public Employees Insurance Agency and the Workers' Compensation Division. The State seeks reimbursement for the health care, medical costs paid, and rehabilitation and work-related programs and services.

- 66. While the State and its various departments, agencies and institutions are struggling to pay for the prescription costs and health care and medical costs associated with OxyContin, defendants continue to reap millions of dollars in profits from the sale of OxyContin.
- 67. Defendants have continued to misinform the state authorities about the necessity of prescribing OxyContin and the appropriate uses of OxyContin.
- 68. In equity and fairness, it is defendants and their agents, not the taxpayers of the State of West Virginia who should bear the costs of the unnecessary and excessive prescription costs or OxyContin and its related diseases and illnesses. By avoiding their own duties to stand financially responsible for the harm done by their product, defendants wrongfully have forced the State to perform such duties and to pay for excessive prescription costs and health care and medical costs and other programs and services associated with OxyContin. As a result, defendants have been unjustly enriched to the extent that taxpayers of the State of West Virginia have had to pay these costs.
- 69. There is no adequate remedy at law that will protect the State from continued irreparable injury or fully compensate the State for the damaged caused to the State by defendants' conduct.
- 70. Wherefore the State prays for relief and judgment against the defendants, jointly and severally, as follows:
- A. For restitution and reimbursement sufficient to cover all prescription costs that the State has incurred related to OxyContin due to defendants' wrongful conduct, with said amount to be determined at trial;

- B. For restitution and reimbursement sufficient to cover all costs expended for health care services and programs associated with the diagnosis and treatment of adverse health consequences of OxyContin use, including but not limited to addiction due to defendants' wrongful conduct, with said amount to be determined at trial:
- C. For restitution and reimbursement for all the prescription costs consumers have incurred related to OxyContin:
- D. For such other and further extraordinary equitable, declaratory and/or injunctive relief as permitted by law as necessary to assure that the State has an effective remedy and to stop defendants' promotion and marketing of OxyContin for inappropriate uses in West Virginia currently and in the future:
  - E. For disgorgement:
- F. For pre-judgment interest, as well as the State's reasonable attorneys' fees. expert witness fees and other costs of this action;
- G. For such other and further relief, as the Court deems just and proper, to which the State may be entitled.

#### COUNT IV

# (INDEMNITY)

- 71. The State realleges and incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows:
- 72. As a direct and proximate result of the breaches of duty and omissions of defendants, the State has paid and continues to pay millions of dollars for prescription drug costs, and the provision of necessary medical care, facilities and services for certain of those

aforementioned citizens of West Virginia who unnecessarily have been prescribed OxyContinand needed health care treatment for OxyContin-related diseases and illnesses.

- 73. The State has been legally obligated to pay the aforementioned sums and has not conducted itself in any wrongful manner in being so obligated to pay and in paying the aforementioned sums.
  - 74. Defendants have been unjustly enriched as a result.
- 75. In all fairness and justice and to prevent unjust enrichment, defendants should indemnify the State for the excessive prescription costs and the treatment of OxyContin-related ailments, including, but not limited to, necessary medical care, facilities and services for citizens of West Virginia who have been unnecessarily and inappropriately prescribed OxyContin and citizens who have needed and continue to need health care treatment for their use of OxyContin.
- 76. Wherefore, the State prays for relief and judgment against the defendants, jointly and severally, as follows:
- A. For restitution and reimbursement sufficient to cover all prescription costs the State has incurred related to OxyContin due to defendants' wrongful conduct, with said amount to be determined at trial;
- B. For restitution and reimbursement sufficient to cover all costs expended for health care services and programs associated with the diagnosis and treatment of adverse health consequences of OxyContin use, including but not limited to addiction due to defendants wrongful conduct, with said amount to be determined at trial:
- C. For restitution and reimbursement for all the prescription costs consumers have incurred related to OxyContin:

- D. For such other and further extraordinary equitable, declaratory and/or injunctive relief as permitted by law as necessary to assure that the State has an effective remedy and to stop defendants' promotion and marketing of OxyContin for inappropriate uses in West Virginia, currently and in the future:
- E. For pre-judgment interest, as well as the State's reasonable attorneys' fees.

  expert witness fees and other costs of this action:
- F. For such other and further relief, as the Court deems just and proper, to which the State may be entitled.

#### COUNT V

### (NEGLIGENCE)

- 77. The State realleges and incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows:
- 78. Defendants had a duty to exercise reasonable care in the manufacture, marketing, promotion, distribution and/or sale of OxyContin.
  - 79. Defendants breached this duty by the conduct alleged above.
- 80. As a proximate result, Defendants and their agents have caused the State to incur excessive prescription costs and health care costs and medical costs related to diagnosis, treatment and cure of addiction or risk of addiction to OxyContin. in that many of these citizens of West Virginia are Medicaid or publicly-funded health care recipients, and the State thus has borne the massive costs of these illnesses and diseases by providing necessary medical care, facilities and services for treatment of OxyContin to citizens of West Virginia who are unable to afford or otherwise obtain such necessary medical care, facilities and services.

- 81. Wherefore, the State prays for relief and judgment against the defendants, jointly and severally, as follows:
- A. For restitution and reimbursement sufficient to cover all prescription costs the State has incurred related to OxyContin due to defendants' wrongful conduct, with said amount to be determined at trial:
- B. For restitution and reimbursement sufficient to cover all costs expended for health care services and programs associated with the diagnosis and treatment of adverse health consequences of OxyContin use, including but not limited to addiction due to defendants' wrongful conduct, with said amount to be determined at trial;
- C. For restitution and reimbursement for all the prescription costs consumers have incurred related to OxyContin;
- D. For pre-judgment interest, as well as the State's reasonable attorneys' fees. expert witness fees and other costs of this action;
- E. For such other and further extraordinary equitable, declaratory and/or injunctive relief as permitted by law as necessary to assure that the State has an effective remedy and to stop defendants' promotion and marketing of OxyContin for inappropriate uses in West Virginia, currently and in the future;
- F. For civil penalties for each violation committed pursuant to the Consumer Credit Protection Act;
- G. For a fund establishing a medical monitoring program due to the increased susceptibility to injuries and irreparable threat to the health of OxyContin users resulting from

their exposure to OxyContin which can only be mitigated or addressed by the creation of a Court-supervised fund, financed by Defendants and which will:

- Notify individuals who use or used OxyContin of the potential harm from OxyContin;
- 2. Aid in the early diagnosis and treatment of resulting injuries through ongoing testing and monitoring of OxyContin use;
- 3. Fund studies and research of the short and long term effects of OxyContin and the possible cures and treatments for the detrimental effects of using OxyContin;
- 4. Accumulate and analyze relevant medical and demographic information from OxyContin users including, but not limited to the results of testing performed on them;
- 5. Create, maintain and operate a "registry" in which relevant demographic and medical information concerning all OxyContin users is gathered, maintained and analyzed; and
- 6. Gather and forward to treating physicians information related to the diagnosis and treatment of injuries which may result from using OxyContin.
- H. For punitive damages in such amount as will sufficiently punish defendants for their conduct in West Virginia and as well serve as an example to prevent a repetition of such conduct in West Virginia in the future;

I. For such other and further relief, as the Court deems just and proper, to which the State may be entitled.

#### COUNT VI

### (MEDICAL MONITORING)

- 82. The State realleges and incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows:
- S3. Through defendants' tortious acts, omissions, and conduct as set forth above users of OxyContin have been significantly exposed to a proven hazardous substance. As a proximate result of such exposure, such users of OxyContin have suffered an increased risk of contracting serious latent disease (in the form of drug addiction and its "co-morbidities," addiction, physician dependence and consequent illness) relative to the general population. This increased risk of disease makes it reasonably necessary for the users of OxyContin to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of the exposure. Monitoring and testing procedures exist which make the early detection and treatment of such injuries or diseases possible.
- 84. Early detection and diagnosis of these injuries and/or diseases is clinically invaluable since it can prevent, reduce and/or significantly delay resulting discomfort, suffering and/or death and since these conditions can often appear asymptomatic absent proper testing.
- Many individuals at risk for injury and or disease resulting from exposure to OxyContin cannot afford to get appropriate testing and/or have not been advised and do not otherwise know of the need to undergo testing. Users of OxyContin also need to be advised of

the availability of monitoring and testing procedures and treatment which will prevent even graver injury.

- 86. The increased susceptibility to injuries and irreparable threat to the health of OxyContin users resulting from their exposure to OxyContin can only be mitigated or addressed by the creation of a Court-supervised fund, financed by Defendants, that will fund a comprehensive medical monitoring program:
  - A. Notifying individuals who use or used OxyContin of the potential harm from OxyContin;
  - B. Aiding in the early diagnosis and treatment of resulting injuries through ongoing testing and monitoring of OxyContin use;
  - C. Funding studies and research of the short and long term effects of OxyContin and the possible cures and treatments for the detrimental effects of using OxyContin;
  - D. Accumulating and analyzing relevant medical and demographic information from OxyContin users including, but not limited to the results of testing performed on them;
  - E. Creating, maintaining and operating a "registry" in which relevant demographic and medical information concerning all OxyContin users is gathered, maintained and analyzed; and
  - F. Gathering and forwarding to treating physicians information related to the diagnosis and treatment of injuries which may result from using OxyContin.

- 87. OxyContin users in West Virginia have no adequate remedy at law in that monetary damages alone do not compensate for the continuing nature of the harm to them, and a monitoring program which notifies them of possible injury and aids in their treatment can prevent the greater harms which may not occur immediately and which may be preventable if proper research is conducted and the health risks are diagnosed and treated before they occur or become worse.
- 88. Without a court-approved medical monitoring program, the relevant product users will not receive prompt medical care which could detect and prolong their productive lives, increase prospects for improvement and minimize disability.

# **COUNT VII**

# (ANTITRUST)

- 89. The State realleges and incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows:
- 90. The Attorney General of the State of West Virginia is empowered by law pursuant to West Virginia Code §§ 47-18-6, 47-18-7 and 47-18-9 to investigate suspected violation of, and to bring actions on behalf of, the State of West Virginia for damages sustained by the State that result from violation of the West Virginia Antitrust Act.
- Defendants, individually and collectively, as described above, have violated said Act in particular, but without limitation. W. Va. Code § 47-18-3(b)(1)(B) and W. Va. Code § 47-18-4, which read in pertinent part:
  - (b) Without limiting the effect of subsection (a) of the section, the following shall be deemed to restrain commerce unreasonably and are unlawful:

(1) A contract, combination or conspiracy between two or more persons:

. . . . .

(B) Fixing, controlling, maintaining, limiting or discontinuing the production, manufacture, mining, sale or supply of any commodity, or the sale or supply of any service, for the purpose or with the effect of fixing, controlling or maintaining the market price rate or fee of the commodity or service....

W. Va. Code § 47-18-3(b)(1)(B).

§ 47-18-4. The establishment, maintenance or use of a monopoly or an attempt to establish a monopoly of trade or commerce, any part of which is within this state, by any persons for the purpose of excluding competition or controlling, fixing or maintaining prices is unlawful.

W. Va. Code § 47-18-4.

- 92. Defendants have utilized unfair and deceptive business practices to obtain dominant market share in the market for narcotic pain medication.
- 93. Defendants' market share has risen exponentially in a short period of time due to its unfair and deceptive business practices in the marketing and promotion of OxyContin, which constitutes unfair competition.
- 94. Defendants' conduct constitutes an attempt to monopolize the narcotic pain medication market.
  - 95. Defendants' conduct constitutes a contract and combination in restraint of trade.
- 96. The State is a person within the meaning of the Antitrust Act and has suffered damages to its property as set out above as the result of the actions of defendants. W. Va. Code § 47-18-9.

- 97. Wherefore, pursuant to the West Virginia Code §§ 47-18-8 and -9, the State hereby prays for relief as provided therein:
  - 1. Treble damages;
  - 2. Reasonable attorneys' fees, filing fees, reasonable costs and reasonable costs of this action. W. Va. Code § 47-18-9;
  - 3. For injunctive relief permitted by law, pursuant to W. Va. Code § 47-18-8:
  - 4. For such other and further relief, as the Court deems just and proper, to which the State may be entitled. W. Va. Code § 47-18-8.

### JURY TRIAL DEMANDED

98. Plaintiff demands a trial by jury to the extent permitted by law.

# RELIEF REQUESTED

WHEREFORE, the Attorney General prays for judgment on behalf of the State of West Virginia and on behalf of consumers and citizens of the State of West Virginia as set forth above.

Respectfully submitted.

STATE OF WEST VIRGINIA, ex rel. DARRELL V. MCGRAW, JR., ATTORNEY GENERAL,

By Counsel,

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